Actulose®

Lactulose
Concentrate oral solution

Presentation : Each 5 ml Actulose oral solution contains 3.35 g Lactulose USP.

Mode of action : The active principle of Lactulose concentrate solution, lactulose, is neither broken down nor absorbed in the stomach and small intestine. In the colon it acts as a substrate for and promotes the growth of naturally occurring glycolytic micro-organisms, and is broken down to lactic acid. The pH of the intestinal contents is lowered, the growth of acidophilic flora is promoted and the putrefactive micro-organisms are suppressed. This reduces the formation of ammonia and amines and their absorption from the gut, thus leading to a fall in blood ammonia levels (responsible for hepatic encephalopathy). By normalising the intestinal flora Lactulose solution ensures the passage of normal stools, without excessive peristalsis.

Indications : Chronic constipation, Chronic portal systemic encephalopathy.

Doses & administration :

Adults (including the elderly):	initially 15 ml twice daily
Children 5 to 10 years:	10 ml twice daily
Children under 5 years:	5 ml twice daily
Babies under 1 year:	2.5 ml twice daily

All dosages should subsequently be adjusted to the needs of the individual. Each dose may if necessary were taken with water or fruit juices, etc.

Hepatic encephalopathy: Adults (including the elderly): Initially 30 - 50 ml (6-10 x 5 ml spoonfuls) three times a day. Subsequently adjust the dose to produce two or three soft stools each day. Children: No dosage recommendations for this indication.

Contra-indications : Contraindicated in patients with galactosaemia and in cases of gastro-intestinal obstruction. The lactose content should be taken into account when treating patients with lactose intolerance.

Drug interactions : None known. Pregnancy: Wide clinical experience, together with data from animal reproduction studies has not revealed any increase in embryotoxic hazard to the foetus, if used in the recommended dosage during pregnancy. If drug therapy is needed pregnancy, the use of this drug is acceptable. Lactation: nursing mothers feeding their offspring can use this product.

Undesireble effect : During the first few days of treatment meteorism and increased flatulence may occur. These symptoms usually disappear under continued therapy. Diarrhoea may occur especially when using higher dosages, e.g. during treatment of portal systemic encephalopathy. Dosage should then be adjusted to obtain two or three formed stools per day. Overdose: No specific antidote. Symptomatic treatment should be given.

Pharmaceuticals precautions : Store at room temperature (below 30° C). Protect from light and humidity.

Commercial pack : Each bottle contains 100 and 200 ml oral solution.

Manufactured by :
Silva
Pharmaceuticals Limited
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